

II. REMARKS/ARGUMENTS

A. Status of Claims

Claims 38 and 47-52 are currently pending. Claims 1-37 and 39-46 were previously cancelled. Claim 38 has been amended herein. It is respectfully submitted that no new matter has been added by virtue of this amendment.

B. Applicants' arguments do comply with 37 CFR 1.111(b)

The Examiner has stated that "Applicants note that their claims contain 'consisting essentially of' language but fail to specifically point out how this limitation can be used to further distinguish the claimed invention from the prior art."

Initially, Applicants note that the present claims have been amended without prejudice to recite "consisting of" terminology with respect to the "analgesic" limitation. Accordingly, the present claims are "closed ended" with respect to this limitation and only encompass (i) N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide (T-614) and/or salts thereof and (ii) oxycodone and/or salts thereof.

As discussed below, this limitation differentiates from the "NSAID" discussion in the Background of the Invention of Baker et al. (U.S. Patent No. 4,569,937), which is relied upon by the Examiner in rejecting the present claims.

C. Rejection under 35 U.S.C. 103 (a) over Baker et al. and Tanaka et al.

In the Office Action, the Examiner rejected claims 38, 47-48, 50-52 under 35 U.S.C. 103 (a) over US 4,569,937 (hereinafter "the Baker reference") and Tanaka et al. Arzneimittel-Forschung (1992) Vol. 42 (7) pages 935-44 (hereinafter "the Tanaka reference").

Applicants respectfully submit that the combination of the Baker reference and the Tanaka reference fail to teach or suggest the presently claimed method of effectively treating pain by administering a combination of two analgesic compounds or pharmaceutically acceptable salts thereof consisting of (i) N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide and/or at least one pharmaceutically acceptable salt thereof; and (ii) oxycodone and/or at least one pharmaceutically acceptable salt thereof.

a. There is no motivation to substitute the ibuprofen in the synergistic combination of the Baker composition with another NSAID

Applicants respectfully submit that the combination of the Baker and Tanaka references fail to provide the motivation to one of ordinary skill in the art to substitute the ibuprofen in the Baker formulation with any other NSAID, let alone N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide, as discussed in the Tanaka reference.

The Baker reference teaches a synergistic combination of narcotic analgesics and ibuprofen. It appears that the Examiner is overlooking the fact that the Baker reference utilizes ibuprofen because of its enhanced analgesic effect it has with oxycodone. There is nothing in the Tanaka reference to suggest that N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide would have this effect also, therefore there is no motivation to substitute the ibuprofen in the Baker composition with N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide. Applicants respectfully point out that the purported invention of the Baker reference is directed to pharmaceutical compositions of narcotic analgesics and ibuprofen which "... exhibit unexpectedly enhanced analgesic activity ..." (See Abstract). The Baker reference is therefore limited to combinations wherein the NSAID is ibuprofen and does not teach or suggest that the purported "unexpectedly enhanced analgesic activity" would occur with an NSAID which is different than ibuprofen.

Applicants further submit that, in view of the above, the Baker reference teaches away from substituting ibuprofen with another NSAID (e.g., N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide), because of the unexpected synergy that it purports for the combination of ibuprofen with a narcotic analgesic. Accordingly, due to this purported synergy, one skilled in the art would be discouraged to combine the Baker reference with the Tanaka reference in order to select an NSAID different than ibuprofen (i.e., N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide) to combine with oxycodone. "A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference would be discouraged from the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.'" See *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998). Therefore, Applicants submit that, as a whole, the Baker reference would steer one of ordinary skill in the art away from combining the Baker reference with the Tanaka reference to select an NSAID different than ibuprofen (i.e., N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide) to combine with oxycodone, for the reasons argued above.

In addition, Applicants submit that modifying the formulation of the Baker reference in view of the Tanaka reference, as proposed by the Examiner, by substituting ibuprofen with N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide would result in a dosage form which is not directed to the principle of operation described in the Baker reference (i.e., the purported synergism of narcotic analgesics and ibuprofen). "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." See MPEP 8th edition, Revision 2, p.2100-132.

- b. The reference to NSAIDs in the Background of the Invention in the Baker reference specifically refers to the limited compounds in the Sunshine reference which do not include N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide**

In the August 10, 2006 Final Office Action, the Examiner stated that "Baker et al. teach pharmaceutical compositions for relieving pain in humans comprising a combination of: a. a narcotic analgesic...and b. ibuprofen (a non-steroidal anti-inflammatory drug or NSAID", and cited to the Baker reference at columns 1-2.

Applicants respectfully point out that column 2 of the Baker reference makes no mention of the term "NSAID". Applicants further point out that the relevant portion of column 1 of the Baker reference states that "[t]his patent discloses that the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone." The phrase "this patent" actually refers to U.S. Patent No. 4,464,376 issued to A. Sunshine et al. (hereinafter "the Sunshine reference"). The two references to the term "NSAID" at column 1, lines 17-27, are the only recitations of the term "NSAID" in the entire patent, and they are with reference to the teachings of the Sunshine reference.

Applicants respectfully point out that the purported invention in the Sunshine reference is directed to combinations of caffeine and NSAIDs; caffeine and narcotic analgesics; and caffeine and NSAIDs/narcotic analgesics. Therefore, the summation that "the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone" is in reference to a combination of three active components, i.e. NSAIDs, narcotic analgesics and caffeine, not the ibuprofen/narcotic analgesic combination of the Baker reference.

Furthermore, Applicants point to the Sunshine reference at column 14, lines 58-61, which recite "[t]he term 'selected NSAID' as used herein is intended to mean any non-narcotic analgesic/nonsteroidal anti-inflammatory compound **falling within one of the five structural categories indicated hereinabove.**" (Emphasis added).

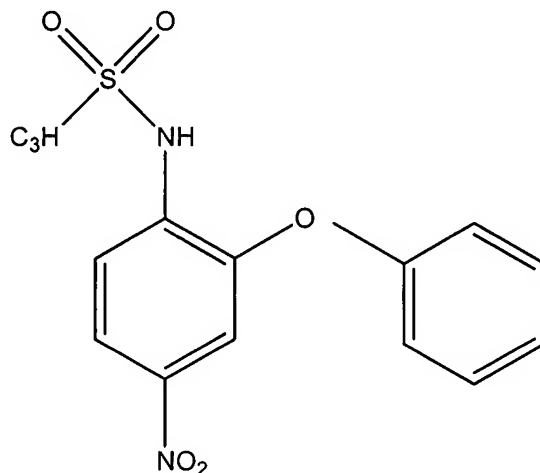
These five categories are set forth at column 7, lines 42-50 of the Sunshine reference which states that:

The non-narcotic analgesics/nonsteroidal anti-inflammatory drugs for use in the compositions and methods of the present invention can be selected from the following categories:

- (1) the propionic acid derivatives;
- (2) the acetic acid derivatives;
- (3) the fenamic acid derivatives;
- (4) the biphenylcarboxylic acid derivatives; and
- (5) the oxicams.

The chemical structures of the (5) categories are exemplified in columns 8-11.

Applicants submit that the chemical structure of the presently claimed NSAID, *i.e.* N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide:



does not fall within any of the five structural categories indicated above. Therefore, even assuming *arguendo* that the Baker reference contemplates the use of other NSAIDs based on the reference to the Sunshine reference, Applicants submit that the "other" NSAIDs would be limited to the five structural categories listed in Sunshine and would not include N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide.

Further, Applicants respectfully submit that it is improper for the Examiner to rely solely on the Background of the Invention of the Baker reference and mischaracterizing the further teaching of this reference. "A prior art reference must be considered in its entirety, *i.e.*,

as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Accordingly, it is Applicants' position that when evaluated as a whole, the Baker reference teaches that ibuprofen provides a synergistic effect in combination with narcotic analgesics and therefore leads away from substituting the ibuprofen with N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide as suggested by the Examiner.

Therefore, it is Applicants position that the Baker reference as a whole does not teach or suggest the use of any NSAIDs other than ibuprofen, as the only mention of "NSAIDs" is in the "Background of the Invention". However, even assuming *arguendo* that the Baker reference teaches other NSAIDs, Applicants submit that the "other" NSAIDs would not include N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide as discussed above with reference to the Sunshine reference.

c. The Tanaka reference does not definitively conclude that N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide is equally efficacious as ibuprofen

In the prosecution history of the present application, the Examiner concluded that "Tanaka et al. only disclose favorable interactions between T-614 and ibuprofen". August 19, 2006 Final Office Action. In making this conclusion, Applicants respectfully submit that the Examiner is relying on only certain portions of the Tanaka reference and appears to be ignoring particular portions of this reference which conclude that N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide was less potent than ibuprofen in particular studies. Therefore, Applicants respectfully submit that the Examiner is not considering the prior art references as a whole and is mischaracterizing the conclusions of the studies performed in the Tanaka reference.

In support of this position, Applicants respectfully point out that, for example, Section 4.2.1 of the Tanaka reference, which states that "[t]he analgesic potency of T-614 in rats was

equal to that of nimesulide and weaker than those of indomethacin and ibuprofen". Tanaka et al. at page 940. Further, the Tanaka reference reports that "T-614 exerts only weak inhibitory effect on UV-erythema [in comparison to ibuprofen] in guinea-pigs which have been demonstrated to be a suitable for antirheumatic drugs." Id at 943.

When viewing the Tanaka reference in its entirety, Applicants submit that that this reference does not definitively conclude that N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide is equally efficacious as ibuprofen, as evidenced by the Tanaka studies referenced above which concluded that T-614 had weaker analgesic potency in rats than ibuprofen and had a weaker effect on inhibition of UV erythema in guinea pigs as compared to ibuprofen. Therefore, Applicants submit that the Tanaka reference fails to provide the motivation to substitute N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide for the ibuprofen utilized in the Baker reference.

d. The Examiner is relying on an improper "obvious to try" rationale

Applicants submit that the Examiner is applying an improper "obvious to try" rationale in suggesting the substitution of ibuprofen with N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide. "In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir.1988). Applicants submit that *In re O'Farrell* is analogous to the present situation, where one of ordinary skill in the art would have to try each of numerous possible NSAIDs in place of ibuprofen in order to arrive at the selection of N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide, as the Baker reference gives no direction as to what NSAIDs other than ibuprofen would be successful.

e. The Examiner is improperly picking and choosing ibuprofen and oxycodone from the prior art

Applicants submit that the Examiner is improperly picking and choosing the N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide of the Tanaka reference and the oxycodone of the Baker reference to recreate the claims of the present application. One "...cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *SmithKline Diagnostics, Inc. v. Helena Laboratories Corporation*, 859 F.2d 878, 887 (Fed. Cir. 1988).

Based on Applicants review of the Baker reference, it appears that the inventors in the Baker reference rejected all NSAIDs in their invention *except* ibuprofen. The purported invention and teachings of the Baker reference are limited to the combination of a narcotic analgesic and ibuprofen. For example, column 1, lines 6 - 9 of the Baker reference states as follows:

This invention relates to pharmaceutical compositions of narcotic analgesics and ibuprofen having analgesic activity in mammals, and to methods of use of the compositions to alleviate pain in mammals.
(Emphasis Added)

Column 2, lines 11-15 of the Baker reference states as follows:

According to the present invention there is provided a pharmaceutical composition comprising a combination of (a) a narcotic analgesic, or a pharmaceutically acceptable salt thereof, and (b) ibuprofen, or a pharmaceutically suitable salt thereof,...
(Emphasis Added)

The following additional passages from the Baker reference are also limited to a combination of narcotic analgesics and ibuprofen:

Column/Lines	Text
Title:	ANALGESIC MIXTURE OF OXYCODONE AND IBUPROFEN

Column/Lines	Text
Abstract:	ABSTRACT Pharmaceutical compositions of narcotic analgesics and ibuprofen . .
Figure 1	ISOBOLOGRAM FOR THE INTERACTION OF ORAL OXYCODONE HCL AND IBUPROFEN . . .
Col. 1, line 1 & 2	ANALGESIC MIXTURE OF OXYCODONE AND IBUPROFEN
Col. 2, lines 20-24	. . . synergistically effective analgesic amounts of oxycodone, or a pharmaceutically suitable salt thereof, and ibuprofen, or a pharmaceutically suitable salt thereof . . .
Col. 2, line 34 & 35	. . . various dose ratios of oxycodone and ibuprofen.
Col. 2, lines 64 & 65	In a composition of the invention, oxycodone and ibuprofen are combined . . .
Col. 3, lines 23 & 24	. . . unexpectedly enhanced analgesic activity of combinations of oxycodone and ibuprofen . . .
Col. 3, lines 53-56	. . . the active ingredient is administered at a daily dosage of from about 0.05 to 7.50 milligrams per kilogram (mg/kg) of body weight of oxycodone and from about 10 to 120 mg/kg of ibuprofen.
Col. 4, lines 24-29	Example 1 Oxycodone/Ibuprofen Tablets Oxycodone HCl 5.0 Ibuprofen 60.0
Col. 4, lines 36-42	Example 2 Oxycodone/Ibuprofen Tablets Oxycodone HCl 5.0 Ibuprofen 300.0
Col. 4, lines 48-55	Example 3 Oxycodone/Ibuprofen Tablets Oxycodone HCl 2.5 Ibuprofen 300.0
Col. 4, lines 60-66	Example 4 Oxycodone/Ibuprofen Capsules Oxycodone HCl 5.0 Ibuprofen 60.0
Col. 5, lines 8-14	Example 5 Oxycodone/Ibuprofen Capsules Oxycodone HCl 5.0 Ibuprofen 300.00
Col. 5, lines 20-26	Example 6 Oxycodone/Ibuprofen Capsules Oxycodone HCl 2.5 Ibuprofen 300.0

Column/Lines	Text
Col. 5, lines 33-39	<p>Example 7</p> <p>Oxycodone/Ibuprofen Tablets</p> <p>Oxymorphone HCl 5.0</p> <p>Ibuprofen 60.0</p>
Col. 5, lines 45-51	<p>Example 8</p> <p>Oxymorphone/Ibuprofen</p> <p>Oxymorphone HCl 5.0</p> <p>Ibuprofen 300.0</p>
Col. 5, lines 58-63	<p>Example 9</p> <p>Oxymorphone/Ibuprofen</p> <p>Oxymorphone HCl 2.5</p> <p>Ibuprofen 300.0</p>
Col. 6, lines 1-7	<p>Example 10</p> <p>Oxymorphone/Ibuprofen Capsules</p> <p>Oxymorphone HCl 5.0</p> <p>Ibuprofen 60.0</p>
Col. 6, lines 13-19	<p>Example 11</p> <p>Oxymorphone/Ibuprofen Capsules</p> <p>Oxymorphone HCl 5.0</p> <p>Ibuprofen 300.0</p>
Col. 6, lines 25-31	<p>Example 12</p> <p>Oxymorphone/Ibuprofen Capsules</p> <p>Oxymorphone HCl 2.5</p> <p>Ibuprofen 300.0</p>
Col. 6, lines 38-43	<p>Example 13</p> <p>Hydrocodone/Ibuprofen Tablets</p> <p>Hydrocodone Bitartrate 5.0</p> <p>Ibuprofen 60.0</p>
Col. 6, lines 49-55	<p>Example 14</p> <p>Hydrocodone/Ibuprofen Tablets</p> <p>Hydrocodone Bitartrate 5.0</p> <p>Ibuprofen 300.0</p>
Col. 6, lines 61-66	<p>Example 15</p> <p>Hydrocodone/Ibuprofen Tablets</p> <p>Hydrocodone Bitartrate 2.5</p> <p>Ibuprofen 300.0</p>
Col. 7, lines 9-14	<p>Example 16</p> <p>Hydrocodone/Ibuprofen Capsules</p> <p>Hydrocodone Bitartrate 5.0</p> <p>Ibuprofen 60.0</p>

Column/Lines	Text
Col. 7, lines 21-27	<p>Example 17</p> <p>Hydrocodone/Ibuprofen Capsules</p> <p>Hydrocodone Bitartrate 5.0</p> <p>Ibuprofen 300.0</p>
Col. 7, lines 33-39	<p>Example 18</p> <p>Hydrocodone/Ibuprofen Capsules</p> <p>Hydrocodone Bitartrate 2.5</p> <p>Ibuprofen 300.0</p>
Col. 7, lines 46-51	<p>Example 19</p> <p>Hydromorphone/Ibuprofen Tablets</p> <p>Hydromorphone HCl 3.0</p> <p>Ibuprofen 60.0</p>
Col. 7, lines 57-63	<p>Example 20</p> <p>Hydromorphone/Ibuprofen Tablets</p> <p>Hydromorphone HCl 3.0</p> <p>Ibuprofen 300.0</p>
Col. 8, lines 1-7	<p>Example 21</p> <p>Hydromorphone/Ibuprofen Tablets</p> <p>Hydromorphone HCl 1.5</p> <p>Ibuprofen 300.0</p>
Col. 8, lines 13-19	<p>Example 22</p> <p>Hydromorphone/Ibuprofen Capsules</p> <p>Hydromorphone HCl 3.0</p> <p>Ibuprofen 60.0</p>
Col. 8, lines 26-31	<p>Example 23</p> <p>Hydromorphone/Ibuprofen Capsules</p> <p>Hydromorphone HCl 3.0</p> <p>Ibuprofen 300.0</p>
Col. 8, lines 37-43	<p>Example 24</p> <p>Hydromorphone/Ibuprofen Capsules</p> <p>Hydromorphone HCl 1.5</p> <p>Ibuprofen 300.0</p>
Col. 8, lines 56-58	All mice are dosed sequentially by the oral route with suspensions of ibuprofen and/or oxycodone hydrochloride solutions.
Col. 8, line 62	A stock suspension of ibuprofen is . . .
Col. 9, lines 22-24	Mice, intubated with various doses of oxycodone hydrochloride, ibuprofen, combined doses of oxycodone hydrochloride and ibuprofen . . .
Col. 9, lines 45-47	In order to study the interaction between oxycodone and ibuprofen, 5 precise dosage ratios of oxycodone hydrochloride and ibuprofen are selected.

Column/Lines	Text
Col. 10, lines 25 & 26	The synergistic interaction of oxycodone hydrochloride and ibuprofen . . .
Col. 10, lines 29-31	. . . the analgesic effect of oxycodone alone is presented in the ordinate, and that of ibuprofen alone is on the abscissa.
Col. 10, lines 32-34	. . . exact fixed dosage ratios based on weight of oxycodone HCl:ibuprofen in the ranges of 1:1.25 to 1:31.1.
Col. 10, lines 35 & 36	. . . representing oxycodone and ibuprofen alone . . .
Col. 10, lines 36-38	. . . representing the compositions of oxycodone and ibuprofen at the fixed dosage ratios.
Col. 11, lines 31-33	. . . straight line additivity hypothesis for oxycodone HCl and ibuprofen . . .
Col. 12, lines 52-54	. . . analgesic synergism is established for all combinations of oxycodone and ibuprofen.
Col. 12, lines 55 & 56	By substitution of the expected analgesic activity of oxycodone alone and ibuprofen alone . . .
Col. 12, lines 62 & 63	. . . it is predicted that oxycodone and ibuprofen would demonstrate analgesic potentiation . . .
Table 1	TABLE 1 ORAL OXYCODONE HCl/IBUPROFEN COMBINATIONS Oxycodone Ibuprofen Oxycodone Ibuprofen
Col. 13, lines 49-55	1. A pharmaceutical composition comprising a synergistic analgesic combination of (a) oxycodone, or a pharmaceutically acceptable salt thereof, and (b) ibuprofen, or a pharmaceutically suitable salt thereof, in which the weight ratio of (a):(b) is from about 1:6 to about 1:400.

As evidenced above, ibuprofen is the only NSAID mentioned throughout the entire reference, and it is the only NSAID exemplified in the Baker formulations.

f. The Examiner is improperly relying on *In re Kerkhoven*

The Examiner also stated in the August 10, 2006 Final Office Action that "the instant situation is amendable to the type of analysis set forth in *In re Kerkhoven*, wherein the court held that it is *prima facie* obvious to combine two (or more) compositions each of which is taught by the prior art to be useful for the same purpose. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Baker reference analgesic composition by substituting T-614 for ibuprofen... "(Emphasis Added)(Citations omitted).

The fact that the Tanaka reference discusses the benefits of N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide over other NSAIDs does not provide the requisite motivation to substitute the ibuprofen of the Baker reference, when the Baker reference visibly contemplates only ibuprofen. Further, even when read in the most favorable light to use NSAIDs other than ibuprofen, a position which the Applicants do not support, the suggestion of other NSAIDs must be interpreted in view of the teachings of the Sunshine reference, which exclude the use of N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide.

Therefore, Applicants respectfully submit that the Examiner's statements indicate that *In re Kerkhoven* is not being properly applied in rejecting the present claims. As stated by the Examiner, the holding of *In re Kerkhoven* is with respect to combining references. However, the Examiner's rejection, is based on modifying the Baker analgesic composition. Applicants respectfully submit that a combination of the Baker analgesic composition with N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide would result in a formulation including a combination of N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide and ibuprofen and an opioid analgesic, and therefore would not result in the presently claimed invention.

Accordingly, in view of the above, Applicants respectfully request that the rejections over the Baker and Tanaka references be removed.

D. Rejection under 35 U.S.C. 103 (a) over Baker et al. and Tanaka et al. in view of Oshlack et al. (US 5,472,712) or Oshlack et al. (US 6,294,195)

In the Office Action, the Examiner further rejected claim 49 under U.S.C. 103 (a) over Baker et al. and Tanaka et al. in view of US 5,472,712 (Oshlack et al.) and US 6,294,195 (Oshlack et al.)

Applicants respectfully submit that, for the reasons discussed above, the Baker reference the Tanaka reference fail to teach or suggest the presently claimed method of effectively treating pain by administering a combination of two analgesic compounds and/or pharmaceutically acceptable salts thereof consisting of (i) N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide and/or at least one pharmaceutically acceptable salt thereof; and (ii) oxycodone and/or at least one pharmaceutically acceptable salt thereof.

Applicants further submit that the Oshlack references also fail to teach or suggest the presently claimed method of effectively treating pain by administering a combination of analgesic compounds consisting essentially of (i) N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide and/or at least one pharmaceutically acceptable salt thereof; and (ii) oxycodone and/or at least one pharmaceutically acceptable salt thereof.

Accordingly, as the Oshlack references fail to cure the deficiencies of the Baker and Tanaka references, Applicants respectfully request that the rejections over the Baker and Tanaka references in view of either Oshlack references be removed.

III. CONCLUSION

In view of the foregoing, it is believed that the application is now in condition for allowance, and applicants respectfully request such action.

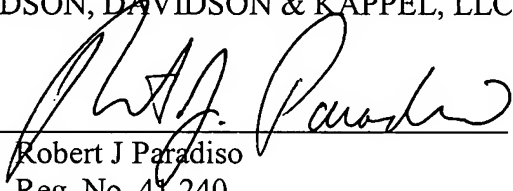
The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Applicants note that a Notice of Appeal was filed and received by the Patent Office on February 15, 2007. Therefore, a response is due July 15, 2007 with a three-month extension of time. As July 15, 2007 fell on a Sunday, this response is being filed on Monday, July 16, 2007 concurrently with a Request for Continued Examination, a Petition for a three-month extension of time and associated fees.

Respectfully submitted,

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